IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: METOPROLOL SUCCINATE END-PAYOR ANTITRUST LITIGATION	)	Civil Action No. 06-71 GMS
THIS DOCUMENT RELATES TO: ALL ACTIONS	)	

CONSOLIDATED CLASS ACTION COMPLAINT

Plaintiffs, identified in paragraphs 24 through 38 herein ("Plaintiffs" or "End-Payor Plaintiffs"), on behalf of themselves and a class of all others similarly situated, hereby seek damages, other monetary relief and equitable relief for Defendants' (AstraZeneca AB, AstraZeneca LP, AstraZeneca Pharmaceuticals LP and Aktiebolaget Hässle) violations of federal and state antitrust laws, state consumer protection laws and state common law principles of unjust enrichment. Plaintiffs allege, upon knowledge as to matters relating to themselves and upon information and belief as to all other matters, as follows:

NATURE OF THE ACTION

1. This consolidated class action complaint alleges violations of federal antitrust and state unfair and deceptive trade practices acts arising from the manufacture and marketing of Toprol-XL® ("Toprol-XL"), on behalf of all end-payors in the United States who purchased Toprol-XL during the Class Period defined below.

2. Toprol-XL (generically known as metoprolol succinate) is an extended-release drug approved by the U.S. Food and Drug Administration ("FDA") that contains an active chemical compound used for the treatment of angina, hypertension and congestive heart failure.

3. Defendants prevented generic versions of Toprol-XL from entering the market, by, *inter alia*, improperly manipulating patent filings and filing baseless patent infringement

lawsuits, thus unlawfully monopolizing and/or attempting to monopolize the domestic market for Toprol-XL and its generic bioequivalents.

4. Specifically, Defendants unlawfully obtained and enforced a monopoly for Toprol-XL and metoprolol succinate through intentional omissions and misrepresentations to the U.S. Patent and Trademark Office ("PTO"). As alleged herein, Defendants obtained U.S. Patent 5,001,161 (the "'161 patent") and U.S. Patent 5,081,154 (the "'154 patent"), through inequitable conduct before the PTO, and caused them to be listed in the Orange Book (defined below) in a manner that has enabled Defendants to falsely create and extend their market monopoly for Toprol-XL. In the absence of such conduct, the '161 and '154 patents would not have been issued. Defendants wrongfully protected their patent-enabled monopoly by filing sham patent infringement litigation, when they knew or should have known that the patents were unenforceable *ab initio*. Defendants' unlawful conduct prevented less expensive generic versions of Toprol-XL from entering the United States market, thereby causing injury to Plaintiffs and other members of the Class.

5. In addition to their invalidity based on Defendants' misconduct before the PTO, the '161 and '154 patents are invalid for double patenting over the earlier issued '318 patent and the '161 patent is not entitled to priority to the '318 patent.

6. As more fully described below, Defendants maintained patents for metoprolol succinate itself, as well as "sustained release" formulations of metoprolol succinate. Toprol-XL sales in 2005 were $1.29 billion, making it the number one revenue producing betablocker (a specific type of drug used to treat hypertension), and AstraZeneca's top-selling drug by volume. Defendants' unlawful actions as described herein have prevented generic versions of Toprol-XL from entering the United States market.

7. As a result of Defendants' conduct, Plaintiffs and the Class (as defined herein) paid millions of dollars for Toprol-XL at prices significantly higher than what they would have paid if competing and/or generic versions of Toprol-XL were on the market.

8. At least three generic drug manufacturers, KV Pharmaceutical Company ("KV"), Andrx Pharmaceuticals, LLC and Andrx Corporation ("Andrx") and Eon Labs, Inc. ("Eon") (collectively, the "generic manufacturers") filed separate Abbreviated New Drug Applications ("ANDAs") with the FDA requesting approval to market a generic version of Toprol-XL. In their applications, the generic manufacturers asserted that their products are bioequivalents to Toprol-XL and either (i) do not infringe any patent owned by or licensed to Defendants or (ii) that Defendants' underlying '161 and '154 patents for Toprol-XL are invalid.

9. Defendants have engaged in anticompetitive conduct designed to prevent competition from manufacturers of generic bioequivalents to Toprol-XL. Defendants' anticompetitive conduct includes improperly obtaining patents '161 and '154 for the purpose of preventing generic competition. As noted above, Defendants also filed baseless patent infringements actions against the generic manufacturers, which have prevented generic versions of Toprol-XL from entering the U.S. market.

10. Defendants instituted these suits to frustrate or delay market availability of generic bioequivalents. The commencement of these actions prevented the FDA from granting final approval of generic manufacturers' ANDAs to manufacture, market and sell a generic version of Toprol-XL under the "Hatch-Waxman Act." Drug Price Competition and Patent Term Restoration Act of 1984; see Pub.L. No. 98-417, 98 Stat.1585 (1984 (codified as amended at 21 U.S.C. § 355 and 35.U.S.C. § 271(e))). The Hatch-Waxman Act was intended to facilitate

entry of generic drugs into the market, but Defendants have used this Act to frustrate and delay generic competition from less expensive, reasonably priced alternatives.

11. Defendants knew that under the Hatch-Waxman Act the mere filing of patent litigation, even groundless suits based on invalid or unenforceable underlying patents, would automatically prevent the FDA, for up to thirty months, from granting generic competitors final approval of an ANDA. Defendants' patents were ultimately determined invalid and unenforceable in Federal District Court,[1] but their lawsuits were nevertheless able to block generic competition for an extended period of time. Their actions have allowed Defendants to unlawfully maintain their monopoly simply by listing the patents in the Orange Book and then filing and pursuing baseless patent infringement litigation against generic competitors.

12. Such unscrupulous strategies by brand name companies have not gone unnoticed by federal competition authorities. The Chairman of the Federal Trade Commission ("FTC"), Timothy Muris ("Muris"), for example, in a recent statement before a Congressional Subcommittee, noted that "an improper Orange Book listing strategy involves unilateral abuse of the Hatch-Waxman process itself to restrain trade." *See* Prepared Statement of The FTC Before the Committee on Energy and Commerce, Subcommittee on Health, United States House of Representatives ("FTC Statement"), at 9 (Oct. 9, 2002). Chairman Muris also explained that because "the FDA does not review patents presented for listing in the Orange Book . . . , an NDA

[1] An opinion issued on January 17, 2006 by Judge Sippel, in the United States District Court for the Eastern District of Missouri, Eastern Division, held that Defendants' patents '161 and '154 were unenforceable due to Defendants' inequitable conduct before the PTO during the prosecution of the patents for failure to disclose a dispute concerning inventorship of metoprolol succinate and were also invalid on the basis of double patenting over the'318 patent. The Court further held that the '161 patent was invalid as anticipated, and not entitled to priority to the '318 patent. *In re Metoprolol Succinate Patent Litigation*, 2006 WL 120343 (E.D. Mo. Jan. 17, 2006). Defendants have appealed this decision.

filer acting in bad faith...[has the] power to . . . delay[] generic entry and potentially cost[] consumers millions, or even billions, of dollars without valid cause." FTC Statement at 10.

13. As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and members of the Class have been denied the benefits of free and unrestrained competition. Plaintiffs and members of the Class have been denied the opportunity to choose between branded Toprol-XL and a lower priced AB-rated generic alternative which would have initially cost thirty percent (30%) to forty percent (40%) less than branded Toprol-XL. Instead, Plaintiffs and members of the Class have been forced to continue to pay supracompetitive prices for Toprol-XL, thereby causing them to sustain injury to their business and property.

JURISDICTION AND VENUE

14. This action is brought under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injuries to Plaintiffs and members of the Class resulting from, *inter alia*, Defendants' violations of the federal antitrust laws, for injunctive relief, and for the costs of suit, including reasonable attorneys' fees. This Court has jurisdiction over this action pursuant to the Class Action Fairness Act of 2005 ("CAFA"), 28 U.S.C. § 1711, *et seq.*, which vests original jurisdiction in federal district court on any multi-state class action where the aggregate amount in controversy exceeds $5,000,000 and the citizenship of any member of the class of plaintiffs is different from any defendant. The diversity and amount in controversy requirements of CAFA are satisfied in this case. The Court also has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337, 15 U.S.C. § 26 and 28 U.S.C. § 1332(d)(2). This Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367(a).

15. Venue is proper in this judicial district pursuant to 15 U.S.C. § 22, and 28 U.S.C. § 1391(b) because Defendants reside, transact business, are found, and/or have agents in this

district, and because a substantial portion of the affected trade and commerce described below has been carried out in this district.

INTERSTATE TRADE AND COMMERCE

16. During all or part of the relevant time period:

(a) Defendants manufactured and sold substantial amounts of Toprol-XL in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States;

(b) Defendants transmitted funds, as well as contracts, bills, and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Toprol-XL; and

(c) Defendants employed, in furtherance of their monopolization and attempt to monopolize, as alleged herein, the United States mails and interstate and international telephone lines, as well as means of interstate and international travel.

17. The illegal monopolization and attempt to monopolize the market for Toprol-XL and its generic bioequivalents alleged herein have substantially affected interstate and foreign commerce.

THE PARTIES

Consumer Plaintiffs

18. Plaintiff Thelma Clement ("Clement") purchased Toprol-XL during the Class Period, and, like other members of the Class, paid more than she would have absent Defendants' unlawful monopolization and attempts to restrict generic access for Toprol-XL.

19. Plaintiff Dorothy Ferguson ("Ferguson") purchased Toprol-XL during the Class Period, and, like other members of the Class, paid more than she would have absent Defendants' unlawful monopolization and attempts to restrict generic access for Toprol-XL.

20. Plaintiff Mary Anne Gross ("Gross") purchased Toprol-XL during the Class Period, and, like other members of the Class, paid more than she would have absent Defendants' unlawful monopolization and attempts to restrict generic access for Toprol-XL.

21. Plaintiff Neil Lefton ("Lefton") purchased Toprol-XL during the Class Period, and, like other members of the Class, paid more than he would have absent Defendants' unlawful monopolization and attempts to restrict generic access for Toprol-XL.

22. Plaintiff Mark S. Merado ("Merado") purchased Toprol-XL during the Class Period, and, like other members of the Class, paid more than he would have absent Defendants' unlawful monopolization and attempts to restrict generic access for Toprol-XL.

Third-Party Payor Plaintiffs

23. Plaintiff A.F. of L. – A.G.C. Building Trades Welfare Plan (the "AFL Plan") is a health and welfare benefit plan with its principal place of business in Mobile, Alabama. The AFL Plan represents participants who have family coverage. Plaintiff AFL Plan purchased and/or paid for Toprol-XL during the Class Period and, along with the other members of the Class, paid more than it would have absent Defendants' unlawful monopolization and successful attempts to restrict generic competition for Toprol-XL.

24. Plaintiff American Federation of State, County, and Municipal Employees District Council 47 Health and Welfare Fund ("District Council 47 Fund") is a health and benefit fund operated for the benefit of present and retired workers of the union and their families. The Fund was established pursuant to a duly executed Trust Agreement for the purpose of providing health benefits, including prescription benefits, to its defined beneficiaries. The Fund maintains its principal place of business in Philadelphia, Pennsylvania. Plaintiff District Council 47 Fund purchased and/or paid for Toprol-XL during the Class Period and, along with the other members

of the Class, paid more than it would have absent Defendants' unlawful monopolization and successful attempts to restrict generic competition for Toprol-XL.

25. Plaintiff District 1199P Health and Welfare Plan, ("District 1199P Fund"), is an employee benefit trust fund. District 1199P Fund maintains its principal place of business at Suite 400, 6345 Flank Drive, Harrisburg, Pennsylvania 17112. Plaintiff at all times relevant to this action was self insured with respect to medical and prescription benefits. Plaintiff provides a prescription drug plan for approximately 2,600 participants, which covers prescriptions for Toprol-XL. Plaintiff District 1199P Fund purchased and/or paid for Toprol-XL during the Class Period and, along with the other members of the Class, paid more than it would have absent Defendants' unlawful monopolization and successful attempts to restrict generic competition for Toprol-XL.

26. Plaintiff International Association of Fire Fighters Local 22 Health and Welfare Fund ("Local 22 Fund") is a health and benefit fund for the benefit of present and retired workers of the union and their families. The Local 22 Fund was established pursuant to a duly executed Trust Agreement for the purpose of providing health benefits, including prescription benefits, to its defined beneficiaries. Local 22 Fund maintains its principal place of business in Philadelphia, Pennsylvania. Plaintiff Local 22 Fund purchased and/or paid for Toprol-XL during the Class Period and, along with the other members of the Class, paid more than it would have absent Defendants' unlawful monopolization and successful attempts to restrict generic competition for Toprol-XL.

27. Plaintiff National Joint Powers Alliance ("NJPA") is a non-profit corporation with its principal place of business in Staples, Minnesota. NJPA is a self-funded cooperative which supplies goods and services to school districts, cities, counties, and other government agencies.

Plaintiff NJPA purchased and/or paid for Toprol-XL during the Class Period and, along with the other members of the Class, paid more than it would have absent Defendants' unlawful monopolization and successful attempts to restrict generic competition for Toprol-XL.

28. Plaintiff Plumbers and Pipefitters Local 572 Health and Welfare Fund ("Local 572 Fund") is a trust fund administered pursuant to the requirements of the Taft-Hartley Act, 29 U.S.C. § 186, by an equal number of trustees appointed by labor representatives and union representatives. Local 572 Fund is an "employee welfare benefit plan" and "employee benefit plan" maintained pursuant to § 302(c)(5) of the Labor Management Relations Act ("LMRA"), 29 U.S.C. § 186 (c)(5), and is defined by § 1002(1) and (3) of the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. § 1001, *et seq.* As such, Local 572 Fund is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. § 1132(d). Local 572 Fund's office is located in Davidson County, Tennessee. Plaintiff Local 572 Fund purchased and/or paid for Toprol-XL during the Class Period and, along with the other members of the Class, paid more than it would have absent Defendants' unlawful monopolization and successful attempts to restrict generic competition for Toprol-XL.

29. Plaintiff Sheet Metal Workers Local 441 Health & Welfare Plan ("Sheet Metal Workers Plan") is a health and welfare benefit plan with its principal place of business in Mobile, Alabama. The Sheet Metal Workers Plan represents participants who have family coverage. Plaintiff Sheet Metal Workers Plan purchased and/or paid for Toprol-XL during the Class Period and, along with the other members of the Class, paid more than it would have absent Defendants' unlawful monopolization and successful attempts to restrict generic competition for Toprol-XL.

30. Plaintiff United Food and Commercial Workers Union Local 1776 and Participating Employers Health and Welfare Fund ("Local 1776 Fund") is a health and benefit fund operated for the benefit of present and retired workers of the union and their families. The Fund was established pursuant to a duly executed Trust Agreement for the purpose of providing health benefits, including prescription benefits, to its defined beneficiaries. The Fund maintains its principal place of business in Plymouth Meeting, Pennsylvania. Plaintiff Local 1776 Fund purchased and/or paid for Toprol-XL during the Class Period and, along with the other members of the Class, paid more than it would have absent Defendants' unlawful monopolization and successful attempts to restrict generic competition for Toprol-XL.

31. Plaintiff United Union of Roofers, Waterproofers and Allied Workers, Local No. 74 Health and Pension Fund ("Local 74 Fund") is a health and pension fund established for the benefit of the union's members. Plaintiff Local 74 Fund purchased and/or paid for Toprol-XL during the Class Period and, along with the other members of the Class, paid more than it would have absent Defendants' unlawful monopolization and successful attempts to restrict generic competition for Toprol-XL.

32. Plaintiff United Union of Roofers, Waterproofers and Allied Workers, Local No. 203 Health and Pension Fund ("Local 203 Fund") is a health and pension fund established for the benefit of the union's members. Plaintiff Local 203 Fund purchased and/or paid for Toprol-XL during the Class Period and, along with the other members of the Class, paid more than it would have absent Defendants' unlawful monopolization and successful attempts to restrict generic competition for Toprol-XL.

33. Defendants' unlawful conduct as alleged herein has caused all Plaintiffs to be injured and will likely cause them to continue to sustain injury if the conduct is allowed to proceed.

Defendants

34. Defendant AstraZeneca AB is a company organized and existing under the laws of Sweden, with its principal place of business in Södertälje, Sweden.

35. Defendant AstraZeneca LP is a limited partnership organized under the laws of Delaware, with its principal place of business in Wilmington, Delaware. AstraZeneca LP holds an approved New Drug Application from the FDA for metoprolol succinate preparations with extended release, which it sells under the brand name Toprol-XL. AstraZeneca LP is a U.S. subsidiary of AstraZeneca PLC.

36. Defendant AstraZeneca Pharmaceuticals LP is a company organized and existing under the laws of Delaware, which distributes, markets, and sells throughout the United States pharmaceutical products including Toprol-XL. Its U.S. headquarters is located in Wilmington, Delaware. AstraZeneca Pharmaceuticals LP is a U.S. Subsidiary of AstraZeneca PLC, and was created as a result of a 1999 merger between Zeneca Pharmaceuticals and Astra Pharmaceuticals.

37. Defendant Aktiebolaget Hässle is a company organized and existing under the laws of Sweden, with its principal place of business in Mölndal, Sweden.

38. Defendants AstraZeneca AB, AstraZeneca LP, AstraZeneca Pharmaceuticals LP and Aktiebolaget Hässle are referred to collectively as "Astra" or "Defendants."

RELEVANT MARKETS

39. To the extent applicable to the claims alleged herein, the relevant product market is the market for the manufacture and sale of Toprol-XL, metoprolol succinate, and all generic bioequivalents rated "AB" by the FDA. The relevant geographic markets are the United States

and its territories as a whole (Counts I and IV) and the Indirect Purchaser States (Counts II and III). At all relevant times, up to and including the present, Defendants' market share in the relevant product and geographic markets was 100%.

BACKGROUND

Federal Regulation of Prescription Drugs

40. The manufacture, marketing, distribution, and sale of prescription drugs is one of the most profitable industries in the United States. The U.S. market accounts for more than 40% of the world's prescription pharmaceutical revenues. The cost of prescription drugs in the United States has been rising at a rate of 14% to 18% per year. In 1997, over $97 billion worth of prescription drugs were dispensed in the United States alone. By 2001, the cost of drugs dispensed in the United States was in the range of $160 billion to $170 billion. In 2004, Toprol-XL worldwide sales were approximately $2 billion.

A. Federal Approval of Pioneer Drugs and the Orange Book

41. In order to market a new drug, the maker of the drug must obtain approval from the FDA. 21 U.S.C. § 355(a). A company seeking FDA approval for a pioneer drug must file a New Drug Application ("NDA"), which, among other things, must include detailed testing data establishing the drug's safety and effectiveness. 21 U.S.C. § 355(b)(1). The NDA must also contain information on each patent that claims the drug or a method of using the drug. 21 U.S.C. § 355(b)(1); (c)(2). More specifically, an NDA filer is required to submit to the FDA:

> [I]nformation on each patent that claims the drug or method of using the drug that is the subject of a new drug application or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product.

21 C.F.R. § 314.53(b). The FDA publishes the patent information that it receives in a publication entitled "Approved Drug Products With Therapeutic Equivalence Evaluations," more commonly known as the "Orange Book," where it can be easily found and consulted by future FDA applicants.

42. Pursuant to 21 U.S.C. § 355(c)(2), if, after its NDA is approved, the pioneer drug manufacturer obtains a new patent that claims the drug or methods of its use, the company must supplement its NDA by submitting information on the new patent within thirty days of issuance. The FDA then lists the new patent in a supplement to the Orange Book. The FDA is required to accept as true the patent information it obtains from patent holders.

43. The FDA employs no adjudicatory or other process to determine whether a patent submitted by an NDA holder qualifies for listing under the applicable regulations. Indeed, the FDA has stated that it lacks the resources and expertise to review the patents submitted in connection with NDAs. *See* 59 Fed. Reg. 50338, 50343 (Oct. 3, 1994) ("FDA does not have the expertise to review patent information . . .").

44. Consequently, the Agency's role in the patent listing process is purely ministerial, and it relies entirely upon the good faith of the NDA holder submitting the patent for listing. *See aaiPharm, Inc. v. Thompson*, 296 F.3d 227, 243 (4th Cir. 2002) (recognizing the FDA's "purely ministerial approach to the Orange Book listing process"); *American Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1084 (D.C. Cir. 2001) ("[The FDA] administers the Hatch-Waxman Amendments in a ministerial fashion simply following the intent of the parties that list patents."); *Purepac Pharm. Co. v. Thompson*, 2002 WL 31840631, *5 (D.D.C. 2002) (recognizing that the duty to ensure that only patents that actually claim approved drugs or methods of use are listed in the Orange Book lies solely with the NDA holders); *Watson Pharm., Inc. v. Henney*, 194 F.

Supp. 2d 442, 445 (D. Md. 2001) ("[I]t is paramount to keep in mind that the FDA, in deciding to make an Orange Book listing, is not acting as a patent tribunal. It has no expertise--much less any statutory franchise--to determine matters of substantive patent law. In making its decision to list a patent, therefore, it is entirely appropriate and reasonable for the FDA to rely on the patentee's declaration as to the coverage . . .").

45. Moreover, the FDA has no administrative procedures for resolving listing disputes. If a party wishes to dispute a listing, it may notify the FDA of its basis for disagreement. 21 C.F.R. § 314.53(f). In response to such a notification, the FDA will simply request the brand-name company confirm the correctness of the listed patent information. *Id.* Unless the brand-name company voluntarily "withdraws or amends its patent information in response to FDA's request, the FDA will not change the patent information in the list." *Id.*

46. This unilateral ability of brand name companies to cause and maintain the listing of even the most manifestly inappropriate/unsustainable patents in the Orange Book creates an opportunity for an unscrupulous brand name manufacturer to wrongfully thwart a generic competitor from bringing a lower priced generic product to market. That is precisely what Defendants did here.

B. Generic Drugs

47. To stem the rising cost of prescription drugs, Congress in 1984 amended the Food, Drug, and Cosmetic Act by adding the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. *See* Pub.L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271(e)). The Hatch-Waxman Amendments were designed to bring cheaper generic drugs to market faster. However, in contravention of this expressed goal, Defendants have used the

Hatch-Waxman Amendments to unlawfully stop generic entry into the market and illegally maintain their Toprol-XL monopoly.

48. The availability of generic drugs has been one of the most effective means of lowering the cost of prescription drugs. A generic drug, which must be approved by the FDA, must contain the identical active drug ingredient as the brand-name drug. Further, the generic drug must demonstrate "the absence of a significant difference in the rate and extent to which the active ingredient . . . becomes available at the site of drug action when administered at the same molar dose under similar conditions. . ." as the brand-name drug. *See* 21 C.F.R. § 320.1(c) and (e).

49. Generic drugs are drugs that the FDA has found to be bioequivalent to brand name drugs, *i.e.*, generic drugs have the same active pharmaceutical ingredient and provide the same therapeutic effects as the pioneer, brand-name drugs. Where a generic drug is bioequivalent to a pioneer or brand-name drug, the FDA assigns the generic drug an "AB" rating.

50. Generic drugs are invariably priced below the branded drugs to which they are bioequivalent. The first generic competitor to enter a market typically does so at a price at least 30% lower than the price of the equivalent brand-name drug and quickly takes a substantial amount of market share away from the brand-name manufacturer. As additional generic competitors come to market, the price of the generic equivalents continues to fall, and their combined market share continues to grow. In some cases, generic competitors sell products equivalent to brand-name prescription drugs for as little as 2% of the price of the brand-name drug, and have captured as much as 90% of the brand-name drug's pre-generic sales. Unless the branded manufacturer lowers its prices to meet competition, a branded drug loses a significant

portion of its market share to generic competitors less than a year after the introduction of generic competition.

51. A 1998 study conducted by the Congressional Budget Office (the "CBO") concluded that generic drugs save consumers and third-party payers between $8 billion and $10 billion each year. A report prepared by the Government Accounting Office in August 2000 observed: "Because generic drugs are not patented and can be copied by different manufacturers, they often face intense competition, which usually results in much lower prices than brand-name drugs."

52. If a generic version of a brand-name drug exists and a prescribing physician has not specifically indicated on the prescription "DAW" or "dispense as written" (or similar indications, the wording of which varies slightly from state to state), then: (a) for consumers covered by most insurance plans, the pharmacist will substitute the generic drug; and (b) for consumers whose purchases are not covered by insurance plans, the pharmacist will offer the consumer the choice of purchasing either the branded drug, or the AB-rated generic at a lower price.

53. Once a physician writes a prescription for a brand-name drug such as Toprol-XL, that prescription defines and limits the market to the drug named or its AB-rated generic equivalent. Only drugs which carry the FDA's AB generic rating may be substituted by a pharmacist for a physician's prescription for a brand-name drug.

54. The price competition engendered by generic drug manufacturers benefits all purchasers of the drug, who are able to buy the same chemical substance at much lower prices. Many health insurance companies and employee benefit plans encourage or require substitution of generic drugs for brand-name drugs in order to lower health care costs. Retail pharmacies

routinely substitute generic drugs for brand-name drugs whenever possible in order to lower their own costs and the costs of their customers.

C. Abbreviated New Drug Applications for Generic Drugs

55. Congress enacted the Hatch-Waxman Act in 1984 to establish an abbreviated process to expedite and facilitate the development, approval and marketing of generic drugs. To effectuate its purpose, the Hatch-Waxman Act permits a generic drug manufacturer to file an ANDA, which incorporates by reference the safety and effectiveness data developed and previously submitted to the FDA by the company that manufactured the original "pioneer" drug. The Act also provides an economic incentive to the manufacturer of the first generic drug to file an ANDA for a particular generic drug – *i.e.*, a 180-day statutory period of market exclusivity, during which time the manufacturer has the right to market its drug free from other generic competition.

56. While Congress wanted to facilitate the entry of generic drugs into the market, at the same time, it also sought to protect the legitimate rights of patent holders from infringement by the marketing of generic versions of their patented product. Accordingly, if the owner of the NDA (*i.e.*, the brand name manufacturer) has listed a patent or patents in the Orange Book in relation to the approved brand drug, an ANDA filer is required, as part of its ANDA, to file a specified certification with respect to each such listed patent. This is so even if the listed patent should not have been listed. Because the FDA does not even remotely review the appropriateness or correctness of an Orange Book listing, even if a generic competitor believes that the patent is improperly listed, it must nevertheless file one of the required certifications, or else its ANDA will be deemed incomplete and not approvable. *See* 21 C.F.R. § 314.53(f) (even if generic applicant disputes the appropriateness of an Orange Book listing, if the brand name company refuses to remove the patent voluntarily, the generic applicant's ANDA "must, despite

any disagreement as to the correctness of the patent information, contain an appropriate certification for each listed patent.").

57. For the purposes of this case, the most significant new information that must be included in the ANDA concerns the generic company's position vis-à-vis the patent that the pioneer manufacturer claims applies to the drug. Specifically, a generic drug maker must certify that the pioneer drug is either: (i) not patented (Paragraph I Certification); (ii) protected by a patent that has expired (Paragraph II Certification); (iii) patented, but setting forth the date the patent will expire (Paragraph III Certification); or (iv) that the pioneer drug's patent is either invalid or will not be infringed by the generic drug (Paragraph IV Certification). 21 U.S.C. § 355(j)(2)(A)(vii). In the case of a patent that has not yet expired, the ANDA applicant's only certification options are Paragraph III or IV certifications. *See id.* Relevant here is the Paragraph IV Certification, which requires the ANDA applicant to give notice of the filing to both the owner of the patent and to the holder of the NDA for the approved drug. 21 U.S.C. § 355(j)(2)(B)(i)(I). If the generic manufacturer makes a Paragraph IV Certification, the ANDA applicant must notify the patent owner of the filing and explain why the patent is invalid or will not be infringed. *See* 21 U.S.C. § 355(j)(2)(A)(vi)(IV).

58. The patent owner, upon receiving a Paragraph IV Certification from an ANDA applicant, has a 45-day statutory period in which to initiate a patent infringement suit against the applicant. *See* 21 U.S.C. § 355(j)(5)(B)(iii). If no action is initiated within 45 days, FDA approval of the generic product is not delayed by patent issues.

59. If an ANDA filer submits a Paragraph IV Certification, under the statute, that certification constitutes a "technical act of infringement" which creates jurisdiction in the federal courts to entertain a patent infringement action, and gives the NDA holder forty-five days from

the date of the notice to institute such an action against the generic manufacturer under 35 U.S.C. § 271(e)(2). *See* 21 U.S.C. § 355(j)(5)(B)(iii). If such a suit is initiated, the FDA's approval of the ANDA is automatically stayed for up to thirty months. 21 U.S.C. § 355(j)(5)(B)(iii).

60. The technical act of infringement created under 35 U.S.C.§ 271(e)(2) by the filing of a Paragraph IV Certification is an artificial construct used to create judicial jurisdiction.

61. The mere filing of an infringement action in response to a Paragraph IV Certification, even one without merit, as here, blocks the entry of a generic competitor, without the brand company ever having to establish likelihood of success on the merits, irreparable harm, and balance of hardships or the public good. Indeed, as a practical matter the brand name company automatically protects its monopoly for up to two and a half years while the infringement action grinds through the court system. This creates a strong incentive for patent holders to file suit against ANDA filers because there are no disgorgement provisions for profits earned by the patent holder during the thirty-month period of exclusivity if a court determines that the suit is without merit.

62. At all times relevant herein, under 21 U.S.C. § 355(j)(5)(B)(iv), the first applicant to submit a substantially complete ANDA with a Paragraph IV Certification for a generic version of a brand-name drug receives a 180-day period of exclusivity before other ANDAs for the same drug can be approved by the FDA. The 180-day exclusivity period begins when the first ANDA applicant either (a) begins selling the generic drug or (b) obtains a final judgment of non-infringement in a patent infringement action, whichever occurs first. Thus, the first generic ANDA applicant has the opportunity to compete directly with the brand-name manufacturer for 180 days without competition from other generic manufacturers. If, however, the patent holder

is able to forestall the events which trigger the start of the 180-day period of exclusivity, it can delay indefinitely the entry of all generic competitors.

63. Defendants have successfully forestalled generic competition to Toprol-XL from entering the market – thereby delaying purchasers the benefits of cheaper, generic extended-release metoprolol succinate products – by obtaining patents improperly through intentional misrepresentations and omissions, fraudulently listing these patents in the Orange Book, and bringing and maintaining sham patent infringement suits based on these patents.

HISTORY OF THE TOPROL-XL RELATED PATENTS

A. The Relevant Patents

64. Defendants manufacture, market and sell "extended release" forms of the drug metoprolol succinate as "Toprol-XL."

65. Defendants contend two patents cover Toprol-XL and bar generic competition: U.S. Patent No. 5,001,161 (the "'161 patent") and U.S. Patent No. 5,081,154 (the "'154 patent").

66. Patent '161 is for the "sustained release" form of metoprolol succinate. The application for the '161 patent was filed on March 25, 1988; it issued on March 19, 1991, and it is set to expire March 19, 2008.

67. Patent '154's sole claim is for the composition of metoprolol succinate itself. The application for the '154 patent was filed on September 28, 1990; it issued on January 14, 1992, and it is set to expire January 14, 2009.

68. As explained below, patents '154 and '161 were invalid when issued as a result of Defendants' misconduct before the PTO in the application process for these patents.

69. As explained further below, even if Defendants did not act improperly before the PTO in the application process for the '161 and '154 patents, they are invalid nonetheless for obviousness-type double patenting (non-statutory double patenting) based on claim 8 of the '318

patent, because the claims in the '161 patent and the '154 patents are a genus of the species described in claim 8 of the '318 patent and as anticipated by prior art.

The '161 Patent

70. The "Abstract" of the '161 patent states that "[t]he present invention relates to metoprolol succinate, a new therapeutically active compound, and pharmaceutical preparations comprising this new compound."

71. The "Description of the Present Invention" states:

> This compound can, in order to be administered orally be treated in accordance with the method proposed in EP-A1-0 040 590. Herein it has been proposed an oral pharmaceutical composition comprising a core containing a therapeutically active compound, which core has been coated with a layer comprising 10 to 85% by weight of an anionic polymer soluble at a pH above 5.5, and 15 to 90% by weight of a water insoluble polymer selected from the group of quarternary ammonium substituted acrylic polymers.
>
> ...
>
> When dosing the ready made product a number of discrete, coated particles/granules corresponding to a therapeutical dose unit of the actual therapeutical compound is administered. When administering, in order to achieve a steady blood plasma level of the therapeutically active compound provided with a coating according to the present invention can be administered together with some particles/granules which are not coated.

72. The sole claim of the '161 patent is for "[a] sustained release pharmaceutical composition comprising meotoprolol succinate together with a pharmaceutically acceptable carrier." The invention consisted of coated forms of metoprolol succinate that provide for extended release of the drug.

The '154 Patent

73. The sole claim in the '154 patent is for the composition of metoprolol succinate itself.

The '318 Patent

74. The '318 patent was applied for on January 10, 1985 and issued on October 25, 1988. It expired on October 25, 2005.[2]

75. The "Abstract" of the '318 patent states that "[t]he present invention relates to a new oral pharmaceutical composition having an improved release of the therapeutically active compound present therein, in the lower part of the gastro-intestinal duct. . . ."

76. The "Background of the Invention" states as follows:

> There exists an everlasting problem within pharmacy to be able to administer a therapeutically active compound as close as possible to the colon or preferably in the colon, in order to thereby to eliminate the risk of adverse influence on the active compound by the gastric juice, or to prevent irritation of the ventricular mucous membranes, or to obtain a therapeutically effect [sic] in the lower part of the gastrointestinal tract.

77. The "Object of the Invention" states as follows:

> It has now surprisingly been shown possible to be able to solve the aforesaid problem by the present invention, which is a pharmaceutical composition in unit dosage form characterized by a core comprising a therapeutically active substance in the form of a weak base or a weak acid, on which core there is provided a first, inner layer of a diffusion membrane in the form of ethyl cellulose and/or a copolymer of polyethyl acrylate, methyl methacrylate, and trimethylammonium ethyl methacrylate chloride, and or which inner layer there is provided a second layer of at least one anionic polymer and/or fatty acid having a pk suba of 4.5 to 7, preferably 6 to 6.5.

78. The "Detailed Description of the Invention" provides in relevant part:

> By means of the present invention the core is protected against attack by gastric juice after ingestion by means of the outer layer comprising an anionic polymer and/or fatty acid having a pk suba of 4.5 to 7. When this outer layer has been removed by dissolution

[2] The application filed claimed priority to the Swedish Patent Application No. 84000845, which was filed on January 10, 1984 by Curt H. Appelgren and Eva C. Eskilsson, and published as European Patent Application EP148811 on July 17, 1985.

> upon passage of the composition into the small intestine with its higher pH, a slow but controlled release of the therapeutically active compound from the core by diffusion through the diffusion membrane occurs due to the difference in concentrations on each side of said membrane. The release takes thereby place at such a rate that 80-90% of the therapeutically active compound has been released after 7 to 10 hrs, which means that the release can take place in a constant pH independent way, and thereby in a very reproducible way.

79. Claim 8 of the '318 patent is set forth below, along with the portions of claims 6 and 7 on which it is dependent:

> 6. Oral pharmaceutical composition having an improved release therefrom of a therapeutcially active compound therein which is soluble in gastric juice, independent of its solubility, having a core comprising the therapeutically active compound, a first inner layer coating on the core, in the form of a diffusion membrane which is a mixture of ethyl cellulose and a copolymer of polyethyl methacrylate-methyl methacrylate-trimethyl ammonium ethylmethacrylate chloride, in a weight relationship between the monomers or the copolymer of 63 to 65:31.7 to 32.3:2.5 to 5, and a second outer layer coating on the inner layer of at least one anionic polymer having a pk suba of 4.5 to 7.
> 7. Pharmaceutical composition according to claim 6, wherein the therapeutically active compound in the core has a solubility in the pH range of 1 to 8 which exceeds 0.5 to 1 g per 100 ml.
> *8. Pharmaceutical composition according to claim 7, wherein the active compound is quindine sulphate, quindine bisuphate, quindine gluconate, quindine hydrochloride, metoprolol tartrate, metoprolol succinate, metoprolol fumarate, or furosemide, 5-aminosalycilic acid, propranolol or alprenolol or a pharmaceutically acceptable salt thereof, or a mixture thereof with another weak base, weak acid, or salt thereof having a pk suba of 1 to 8.* (emphasis added).

B. The '161 and '154 Patents Were Obtained Improperly Through Misconduct

80. Patent applicants are required to prosecute patent applications in the PTO with candor, good faith, and honesty. *See Semiconductor Energy Lab. Co., Ltd. v. Samsung Elecs. Co. Ltd.*, 204 F.3d 1368, 1373 (Fed. Cir. 2000); *Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co.*, 324 U.S. 806, 818 (1945). Each individual associated with the filing or

prosecution of a patent application has a specific duty of candor and good faith in dealing with the PTO. This includes each inventor named in the application, each attorney or agent who prepares or prosecutes the application, each person who executes a declaration for submission to the PTO during prosecution of the application, and every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, the assignee or with anyone to whom there is an obligation to assign the application. The duty of candor and good faith dealing includes a duty to disclose to the PTO all information known to such individuals which is material to the patentability of the claimed invention. (*See* 37 C.F.R. § 1.56). Breach of that duty constitutes inequitable conduct.

81. Inequitable conduct consists of an affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false or misleading material information, coupled with intent to deceive.

82. The actions and omissions of those associated with the filing and/or prosecution of the patents at issue here, as set forth below, constitute clear and convincing evidence of (a) intent to deceive the Patent Office, and (b) inequitable conduct.

83. Prior to the PTO amending its rules in March, 1992, information was deemed material if "a reasonable examiner would substantially likely consider [it] important in deciding whether to allow an application to issue as a patent." *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1363 (Fed. Cir. 2003) (internal citations omitted). Subsequent to the PTO amending its rules, information is deemed material if it "establishes either 'a prima facie case of unpatentability' or 'refutes, or is inconsistent with a position the applicant takes.'" *Id.* at 1363-64 n.10. However, the new standard established by the PTO was not intended to

"constitute a significant substantive break with the previous standard." *Hoffman-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1368 n.2 (Fed. Cir. 2003).

84. Defendants failed to disclose to the PTO material information that would have affected the patentability of the claims regarding Toprol-XL. Specifically the Defendants (1) failed to disclose to the PTO that they were involved in a lengthy contest over the inventorship of metoprolol; and (2) also failed to name the correct inventors in their prosecution of the subject patents.

History of the Invention of Metoprolol Succinate

85. In 1971, an Astra[3] scientist named Toivo Nitenberg synthesized metoprolol succinate and the tartrate and sulfate salts of metoprolol. At that time, Astra chose to commercialize only the tartrate salts.

86. In the 1980's, Astra wanted to develop a formulation of metoprolol that could be used for once-daily dosage, which the tartrate salts could not. As a result, Astra formed a research group to develop an extended release formulation of metoprolol. This group included scientists Curt Appelgren and Eva Eskilsson.

87. In 1982, Appelgren (along with his Astra colleague Ulf Jonsson) met with Urban Stenhede, a chemist in Astra's Södertälje, Sweden facility. Appelgren and Jonsson asked Stenhede to manufacture metoprolol salts with lower solubility than the tartrate salts.

88. In turn, Stanhede asked Lars Lilljequist, a chemist, to manufacture metoprolol salts with lower solubility than in the tartrate salts. He did; Lilljequist synthesized metoprolol succinate.

[3] "Astra" includes Hassle, as the division of the Company was named at this time.

89. Then, in December 1982, Appelgren left Astra to form Lejus Medical ("Lejus"), a Swedish pharmaceutical research and development company. Eskilsson joined him at Lejus a few months thereafter.

90. Lejus filed a patent application in Sweden (SE 8400085) for delayed and extended release dosage forms of pharmaceutical compositions, including metoprolol succinate, on January 10, 1984. Appelgren and Eskilsson were named as the inventors on the patent application. The Swedish patent was published on July 17, 1985 as EP 148811.

91. On January 1, 1985, Lejus filed the same application in the United States, Application No. 690,197 (the '197 application) which eventually issued as the '318 patent on October 25, 1988.

92. In July, 1985, Astra became aware of the Swedish patent and maintained that it was improper in that (1) metoprolol succinate was invented by its employee, Nitenberg, in 1971; and (2) Astra was also responsible for extended release formulations of metoprolol succinate.

93. At that time, Astra recognized that the publication of the patent on July 17, 1985 could, from that point forward, be cited as prior art to and possibly invalidate later applications concerning metoprolol succinate, thereby threatening Astra's market position, as the invention was now known to the public.

94. On October 21, 1985, Astra filed an action with the Swedish Patent Office to transfer the inventions contained in EP 148811 that relate to metoprolol succinate to Astra. In its action, Astra claimed that Nitenberg was the actual inventor of metoprolol succinate and that Appelgren and Eskilsson only worked with preparations already invented by Nitenberg.

95. In the Fall of 1985, Astra advised Lejus that metoprolol succinate was invented by Nitenberg and Lejus agreed to file new patents on the metoprolol succinate inventions and assign the applications to Astra. Astra then withdrew its action with the Swedish Patent Office.

96. In January, 1986, Lejus filed Swedish patent application 8600202-9, for metoprolol succinate inventions.

97. In February, 1988, Astra again asserted its position to Lejus, that Nitenberg, and not Appelgren and Eskilsson, was the inventor of metoprolol succinate and that Nitenberg should be named as the inventor and Appelgren and Eskilsson named only as co-inventors for inventing a particular form of a pharmaceutical composition under the claim.

98. In March 1988, Lejus filed U.S. patent application 172,897 (application '897) (which eventually issued as the '161 patent) as a counterpart to Swedish patent application 8600202-9. The application claims (1) metoprolol succinate; and (2) "a pharmaceutical composition, characterized in that the active compound is metoprolol succinate." The application named only Appelgren and Eskilsson as inventors.

99. The '897 application was filed as a continuation in part of the '197 application, filed on January 10, 1985, in an effort to avoid the problem, previously identified by Astra, of the prior art of the published EP 148811 patent.

100. Thus, by filing the '897 application as a continuation in part of the '197 application, and by naming the identical inventors, Astra intended to reap the benefit of priority of the '897 application filing date.

101. In May, 1988, Astra confirmed assignment of the Lejus European and United States patents to Astra. Again, Astra maintained that Nitenberg was the inventor of metoprolol succinate and that Appelgren and Eskilsson should be limited in their roles.

102. Nonetheless, during the prosecution of the '161 and '154 patents, Defendants failed to disclose to the PTO any facts relating to their action against Lejus in the Swedish Patent Office in October 1985, the assignment agreement reached between Astra and Lejus, or that Nitenberg had made metoprolol succinate at Astra in 1971.

Effect of Defendants' Conduct

103. Appelgren and Eskilsson were improperly named as inventors, which, as is evidenced by their dispute with Lejus, was both untrue and material.

104. The issue of inventorship is highly material in the patent prosecution process.

105. The failure to disclose the dispute regarding inventorship of metoprolol succinate to the PTO was both material (*i.e.*, there was a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent) and done with an intent to deceive the patent examiner. *See PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1321 (Fed. Cir. 2000) (disputes concerning inventorship are material information that needs to be disclosed) (citing Manual of Patent Examining Procedure § 2001.06(c) and § 2004).

106. Had Defendants disclosed material information concerning the ongoing dispute over inventorship of metoprolol succinate and/or that incorrect inventors were listed on the patent applications, this would have undoubtedly affected a reasonable patent examiner's decision to issue a patent.

107. Accordingly, the '161 and 154 patents were and are unenforceable *ab initio*, and Defendants at no time could have reasonably asserted a patent claim on the basis of these inequitably obtained patents. Nor could Defendants reasonably have believed that a claim of infringement of these patents could reasonably be asserted against a proposed generic manufacturer of Toprol-XL.

C. Even if Defendants Acted Properly Before the U.S. PTO, the '161 and '154 Patents are Nonetheless Invalid

The '161 and '154 Patents are Invalid for Double Patenting Over the '318 Patent

108. The doctrine of non-statutory double patenting (also known as "obviousness-type" double patenting) prevents the issuance of a patent on claims that are nearly identical to claims in an earlier patent. This doctrine prevents an applicant from extending patent protection for an invention beyond the statutory term by claiming a slight variant.

109. When patent holders try to wrongfully extend the period of exclusivity by filing claims in a later patent that are not distinct from earlier claims, a court will invalidate the claims that are not patently distinct from an earlier patent because of obviousness-type double patenting. *See Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 189 F. Supp. 2d 377, 381 (E.D. Va. Feb. 25, 2002). A later patent is not patently distinct from an earlier claim if the later claim is obvious or inevitable in light of an earlier claim. If a later claim is anticipated by an earlier claim, there can be no patentable distinction. *Id.*

110. The doctrine of "obviousness-type double patenting" applies, and "requires elimination of the extension of exclusivity by truncating the term of the second patent to issue, to coincide with the term of the first patent to issue." *Eli Lilly and Co. v. Barr Laboratories, Inc.*, 251 F. 3d 955, 957 (Fed. Cir. 2001).

111. A species/genus relationship is a type of double patenting wherein the second broader claim is held invalid because it is anticipated by, and therefore not patently distinct from an earlier species claim. Claim 8 of the '318 patent discloses a specific application from within the general scope of the '161 patent's claim. Thus, the '161 patent is invalid as a "genus" of claim 8's "species." *See In re Goodman*, 11 F.3d 1046, 1053 (Fed. Cir. 1993); *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 971 (Fed. Cir. 2001); *Geneva Pharmaceuticals, Inc. v.*

GlaxoSmithKline PLC, 349 F.3d 137, 1383 (Fed. Cir. 2003) (defining a species and genus relationship as one in which the second broader claim is invalid because it is anticipated by, and therefore not patently distinct from, an earlier species claim, making it invalid double patenting).

112. Specifically, the claim in the '161 patent for "sustained release" formulations of metoprolol succinate is an obvious variant of claim 8. Claim 8 of the '318 patent is a particular type of a controlled release formulation of metoprolol succinate and the claim of the '161 patent is a broad generalized claim to controlled release formulations of metoprolol succinate.

113. The claim in the '154 patent is only for the metoprolol succinate compound, and thus clearly not patentable in light of claim 8. Likewise, the '154 patent, which claims any pharmaceutical compositions containing metoprolol succinate, is a genus of the species in claim 8 of the '318 patent.

The '161 Patent is Invalid as Anticipated by Prior Art Under 35 U.S.C. § 102(b)

114. A claim in a later-filed patent application may claim priority to an earlier-filed patent application under 35 U.S.C. § 120 if the earlier application complies with the written description requirement of paragraph one of 35 U.S.C. § 112, which requires that the specification "contain a written description of the invention, and of the manner and process of making and using it." *See e.g., Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1158 (Fed. Cir. 1998) (to meet section 112's requirement, "the disclosure of the earlier application, the parent, must reasonably convey to one of skill in the art that the inventor possessed the later-claimed subject matter at the time the application was filed") (internal citations omitted).

115. The '161 patent was not entitled to priority to the '318 patent application.

116. The specification contained in the '318 patent does not reasonably convey to one of skill in the art that the inventor of the '318 patent possessed the subject matter of the '161 patent at the time the '318 application was filed. In order to be entitled to a priority, the

disclosure in the '318 patent would have been required to describe the '161 patent invention, including all of its limitations; this information is absent from the '318 patent.

117. The effective filing date for the '161 patent is March 25, 1988.

118. Swedish application 84000845, published July 17, 1985, is the parent of the '318 patent and the grandparent of the '161 patent. Because the species of sustained release metoprolol succinate that becomes claim 8 of the '318 patent in the Swedish application was published in July 1985, more than one year before the March 1988 filing of the '161 patent application, the '161 patent is invalid under 35 U.S.C. § 102(b), which stands for the proposition that a person is entitled to a patent unless the invention was described in a printed publication more than one year before the patent application was filed in the United States.[4]

Defendants' Filing of a Disclaimer of Claim 8 of the '318 Patent

119. Claim 8 of Defendants' '318 patent, which issued on October 25, 1988 (expiring on October 25, 2005), claims, among other compounds, "metoprolol succinate."

120. The claims of the '161 and '154 patents also claim "metoprolol succinate," but are due to expire on March 18, 2008, which is more than 17 years after the issuance of the '318 patent.

121. Defendants knew that the Patent Act (as it existed when the '318 patent was filed) entitled them to only 17 years of patent protection for metoprolol succinate and that the Patent Act prohibited them from "double patenting" metoprolol succinate for the purpose of obtaining

[4] In addition, the '161 Patent was anticipated by U.S. Patent No. 4,957,745 (the "'745 patent"), which was issued from a continuation of the U.S. Patent application that claimed priority to Swedish Patent Application No. 8504721, which was filed on October 11, 1985 (naming as inventors Ulf E. Jonsson, John A. Sandberg and John A. Sjogren) and published as UK Patent Application GB2,181,348 on April 23, 1987. The application for the '745 Patent was filed on February 14, 1989; it issued on September 18, 1990 and is set to expire on September 18, 2007. The '745 Patent includes another controlled release formulation of metoprolol succinate.

more than 17 years of patent protection. However, Defendants did not file any terminal disclaimers limiting the patent monopoly for metoprolol succinate to 17 years.

122. Because Defendants did not file terminal disclaimers for the'161 and '154 patents, they are invalid for obviousness-type double patenting due to claim 8 of the '318 patent, and Defendants knew this.

123. On November 21, 2003, Defendants filed a statutory disclaimer of claim 8 of the '318 patent, effectively canceling the claim.

DEFENDANTS' IMPROPER LISTING OF PATENTS IN THE ORANGE BOOK

124. Despite Defendants' knowledge that the '161 and '154 patents were invalid, the Defendants caused the patents to be listed in the Orange Book as covering Toprol-XL in order to force generic applicants to submit Paragraph IV certifications to the listed patents, resulting in Defendants' ability to commence approval-blocking patent litigation against those generic applicants. Defendants did not withdraw the patents from the Orange Book even after being provided with clear proof that they were improperly filed.

125. Defendants knew under the Hatch-Waxman Act that if they filed patent infringement actions in response to the Paragraph IV certifications (that Defendants knew would be triggered by their wrongful Orange Book listings), they would be able to delay FDA final approval of ANDAs filed by generic competitors, thereby barring generic entry for up to thirty (30) months.

126. Given the unambiguous listing prohibition set forth in 21 C.F.R. § 314.53(b), Defendants plainly and intentionally violated federal law by listing the patents as part of their scheme to block generic Toprol-XL from the market. Unfortunately, it has become common practice in the pharmaceutical industry for brand companies to flout FDA Regulations and list any and every patent they can in the Orange Book so as to force generic manufacturers to file

Paragraph IV Certifications. *See Purepac Pharm. Co. v. Thompson*, 2002 WL 31840631 at *14 ("while the regulations tell those parties what they are supposed to do, they do not actually keep non-conforming patents, submitted in violation of the rules, out of the Orange Book... A utopian rule does not automatically create a utopia").

127. Defendants' listing of the '161 and '154 patents was objectively and subjectively baseless. The improper listing of the patents in the Orange Book was an indispensable predicate act of Defendants' monopoly-preserving scheme, without which Defendants could not have instituted generic entry blocking patent litigation – the mere filing of which, regardless of underlying merit, automatically precluded the FDA from granting approval to the generic applicants for up to thirty months.

128. As a result, Defendants were able to do more than just block all generic applicants from getting FDA approval. By simply listing their patents and forcing the generic applicants to file Paragraph IV Certifications in response thereto, Defendants illegally helped themselves to an additional anti-competitive benefit -- namely, the assurance that even when a generic would be finally introduced into the market, for a six month period the number of generic competitors and the extent of price competition would still be substantially diminished -- as a result of Defendants' misconduct.

129. As described above, it has become fairly established in the marketplace that after the expiration of the first generic's six months of exclusivity, and as more generics enter the market, prices drop significantly, resulting in dramatic savings for consumers. *See* FTC Statement at 18 (recognizing that generic price decreases, and the corresponding benefits to consumers, occur when additional generic competitors enter the market after the expiration of the 180 day exclusivity period).

DEFENDANTS' SHAM INFRINGEMENT ACTIONS IN RESPONSE TO GENERIC MANUFACTURERS' ANDAS

130. KV, Andrx and Eon (the generic manufacturers) manufacture generic pharmaceutical products. They submitted ANDAs to obtain FDA approval for the manufacture and sale of a generic version of oral tablets of metoprolol succinate before the expiration of the '161 and '154 patents.

131. In conformity with the Hatch-Waxman Act, the generic manufacturers' ANDAs contained a Paragraph IV certification for the '161 and '154 patents, asserting that each is invalid, unenforceable and/or would not be infringed by their generic products.

132. Pursuant to 21 U.S.C. §355(j)(2)(B)(i) and (ii), the generic manufacturers gave written notice to Defendants, via letter, that their ANDAs and the accompanying certifications had been filed with the FDA. In accordance with 21 U.S.C. §3550(2)(B)(ii), the notices also set forth the legal and factual bases for their claims that the '161 and '154 patents were either invalid or would not be infringed by their ANDAs.

133. Knowing the '161 and '154 patents were invalid, Defendants commenced multiple patent-infringement suits in the U.S. District Court for the District of Delaware[5] against the following companies seeking to market generic, bioequivalent versions of Toprol-XL: KV, Andrx, and Eon. These cases are summarized in the following chart:

AstraZeneca's Sham Litigations Against Generic Manufacturers			
Generic Manufacturer	**Date Filed**	**District**	**Case Number**
KV Pharmaceutical Co.	May 6, 2003 Aug. 22, 2003	E.D. Missouri E.D. Missouri	4:03-cv-00592-RWS 4:03-cv-01169-RWS
Andrx Pharmaceuticals, LLC Andrx Corporation	Feb. 5, 2004	D. Delaware	1:04-cv-00080-SLR
Eon Labs, Inc.	Apr. 5, 2004	D. Delaware	1:04-cv-00205-SLR

[5] The cases were subsequently transferred to the United States District Court for the Eastern District of Missouri by the Judicial Panel on MultiDistrict Litigation.

134. Defendants' filing of the sham infringement actions resulted in the aforementioned 30-month automatic statutory stay of the FDA's authority to grant final marketing approval to the generic manufacturers for their ANDAs for Toprol-XL. The FDA could not grant final marketing approval to the generic manufacturers until they prevailed in the infringement actions or until the expiration of 30 months, whichever came first.

135. In defense, the generic manufacturers asserted that the '161 and '154 patents were invalid, unenforceable and/or not subject to infringement by their formulation of Toprol-XL, and they counterclaimed.

136. Defendants knew that their infringement actions against the generic manufacturers were a sham, yet they maintained the actions and defended against counterclaims asserted by the generic manufacturers, for the improper purpose of maintaining a monopoly in the Relevant Markets and concealing by deceit that unlawful interference and monopoly maintenance.

137. Defendants continued to maintain the sham Orange Book listings, the sham infringement actions, and their sham defenses of the counterclaim knowingly, intentionally, affirmatively, with the purpose of unlawfully maintaining their monopoly in the Relevant Markets, and with the effect of affirmatively and continuously foreclosing the generic entry of Toprol-XL into the Relevant Markets.

138. Defendants' litigations were objectively baseless and commenced and maintained in bad faith, with the specific intent and subjective motivation to prevent the generic manufacturers from selling competing metoprolol succinate products. The litigations were predicated upon deceptive conduct before the PTO and the FDA and other such conduct, including during the patent infringement litigations. As Judge Sippel noted, during the litigation,

Defendants "maintained a pattern of submitting witness declarations that contradict their own prior deposition testimony." *See In re Metoprolol Succinate Patent Litigation*, 2006 WL 120343, at *21, and Footnote 1, *infra*.

139. Defendants knew they could not expect success on the merits of these litigations, but utilized the Hatch-Waxman process to bar the generic manufacturers from entering the market.

140. On January 17, 2006, the United States District Court for the Eastern District of Missouri granted summary judgment to the generic manufacturers. In relevant part, the Court found, by clear and convincing evidence that:

a) the '161 patent and the '154 patent were unenforceable based on Astra's inequitable conduct in the prosecution of these patents in failing to disclose its material dispute with Lejus over the inventorship of metoprolol succinate to avoid invalidation by prior art;

b) the '161 patent and the '154 patent were invalid based on double patenting over the '318 patent; and

c) the '161 patent was invalid as anticipated and not entitled to priority to the date of the filing of the '318 patent.

See In re Metoprolol Succinate Patent Litigation, 2006 WL 120343, at *25-26.

141. Defendants knew they could not expect success on the merits of these litigations, but utilized the Hatch-Waxman process to bar the generic manufacturers from entering the market.

142. Throughout the course of the proceedings before the PTO and during the litigation of the infringement action, Defendants knowingly and willfully concealed the true facts about their misrepresentations to the PTO to wrongfully obtain the patents described herein and to

wrongfully prevent and discourage lawful competition with their brand name product Toprol-XL.

143. This concealment as described above prevented Plaintiffs and the Class from learning the truth about Defendants' illegal conduct which would have allowed earlier actions to be commenced. At all times, Plaintiffs were kept in ignorance of the information necessary to know that Defendants had engaged in wrongful conduct or that Plaintiffs had been harmed by such conduct.

CLASS ACTION ALLEGATIONS

144. Plaintiffs bring this action pursuant to Rule 23 of the Federal Rules of Civil Procedure, specifically Rules 23(b)(2) and 23(b)(3), on behalf of the following class (the "Class"):

> All persons or entities (including assignees) throughout the United States and its territories who purchased and/or paid for Toprol-XL during the period May 5, 2005 to the present (the "Class Period") for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries (the "Class"). For purposes of the Class definition, persons and entities "purchased" Toprol-XL if they paid some or all of the purchase price.

145. Excluded from the Class are Defendants and their respective subsidiaries and affiliates, all governmental entities, agencies, and instrumentalities, and all persons or entities that purchased Toprol-XL for purposes of resale.

146. Plaintiffs believe that hundreds of thousands of Americans have purchased Toprol-XL. Thus, members of the Class are numerous and joinder is impracticable. The exact number of persons is currently unknown to Plaintiffs, but known to Defendants and/or ascertainable from appropriate discovery.

147. Among the questions of law and fact common to the Class are:

a) Whether Defendants have unlawfully monopolized or attempted to monopolize the market for Toprol-XL and its generic equivalents;

b) Whether Defendants' '161 and '154 patents were obtained through inequitable conduct and whether Defendants wrongfully listed these patents in the Orange Book;

c) Whether Defendants' suits asserting infringements of the '161 and '154 patents were objectively baseless;

d) Whether Defendants possessed and/or unlawfully extended their monopoly power over the market for Toprol-XL and its generic equivalents;

e) Whether Defendants, through their monopolization and/or attempted monopolization, have caused the prices of Toprol-XL to be maintained at supra-competitive levels;

f) Whether the Class suffered and continues to suffer antitrust injury; and

g) Whether Defendants were and continue to be unjustly enriched to the detriment of the Class, entitling Plaintiffs and the Class to disgorgement of all monies resulting therefrom.

148. Plaintiffs' claims are typical of the Class because Plaintiffs and all members of the Class were injured and continue to be injured in the same manner by Defendants' unlawful, anti-competitive and inequitable methods, acts and practices, and wrongful conduct in the conspiracies complained of herein, *i.e.*, they have paid supra-competitive and artificially high prices for Toprol-XL and will continue to be forced to do so until the markets for Toprol-XL and its generic equivalents are competitive and prices reach competitive levels.

149. Plaintiffs will fully and adequately protect the interests of all members of the Class. Plaintiffs have retained counsel who are experienced in antitrust class action litigation. Plaintiffs have no interests which are adverse to, or in conflict with, other members of the Class. The questions of law and fact common to the members of the Class predominate over any questions which may affect only individual members.

150. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. The Class is readily definable and prosecution as a class action will eliminate the possibility of duplicative litigation, while also providing redress for claims which would otherwise be too small to support the expense of individual, complex litigation. Defendants have acted or refused to act, as alleged herein, on grounds generally applicable to the Class, thereby making appropriate final injunctive relief and/or corresponding declaratory relief with respect to the Class as a whole.

COUNT I

FOR DECLARATORY AND INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR DEFENDANTS' VIOLATIONS OF SECTION 2 OF THE SHERMAN ACT

151. Plaintiffs incorporate by reference herein and reallege the preceding paragraphs of this Complaint as fully set forth herein.

152. Defendants' filing of obviously invalid patents violates § 2 of the Sherman Act.

153. The intended effect of these baseless patent filings was to delay the introduction of generic formulations of Toprol-XL into the market.

154. The result of Defendants' unlawful conduct has been to obtain and extend their monopoly in the relevant markets for Toprol-XL and its bioequivalents. This course of conduct included, *inter alia*, the following acts: (i) the intentional omission of material facts from the

PTO; (ii) the prosecution of baseless, sham patent litigation against generic competitors; and (iii) maintaining sham defenses to the counterclaim by the generic manufacturers.

155. Plaintiffs and the other members of the Class have been injured in their business or property by reason of Defendants' antitrust violation alleged in this Count. Their injury consists of being deprived of the ability to purchase less expensive, generic versions of Toprol-XL, and paying higher prices for metoprolol succinate products than they would have paid in the absence of the antitrust violation. The injury to Plaintiffs and the Class is the type of injury antitrust laws were designed to prevent, and the injury flows from Defendants' unlawful conduct.

156. Plaintiffs and the Class are entitled to a declaration that Defendants' monopolization and attempts to monopolize the market for Toprol-XL and its generic equivalents are in violation § 2 of the Sherman Act.

157. Plaintiffs and the Class are entitled to an injunction pursuant to § 16 of the Clayton Act enjoining Defendants' continued monopolistic practices.

158. Plaintiffs and the Class have no adequate remedy at law.

COUNT II

FOR DAMAGES UNDER THE STATUTES OF THE INDIRECT PURCHASER STATES

159. Plaintiffs incorporate by reference herein and reallege the preceding paragraphs of this Complaint as if fully set forth herein.

160. Defendants' conduct described herein constitutes unlawful acts of monopolization and attempts to monopolize, as well as prohibited practices and unconscionable conduct under the antitrust and/or unfair and deceptive trade practices acts of the Indirect Purchaser States, as follows:

a. Arizona: The aforementioned practices by Defendants were and are in violation of the Arizona Uniform State Antitrust Act, Ariz. Rev. Stat. §§ 44-1401, *et seq.*, the Arizona Consumer Fraud Act, Ariz. Rev, Stat §§ 44-1521, *et seq.*, and the Constitution of the State of Arizona, Article 14, §15;

b. California: The aforementioned practices by Defendants were and are in violation of the Cartwright Act, Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and the California Unfair Competition Act, Cal. Bus. & Prof. Code §§ 17200, *et seq.*;

c. District of Columbia: The aforementioned practices by Defendants were and are in violation of the District of Columbia Antitrust Act, D.C. Code §§ 28-4501, *et seq.*;

d. Florida: The aforementioned practices by Defendants were and are in violation of the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat, Ann. §§ 501.201, *et seq.*;

e. Hawaii: The aforementioned practices by Defendants were and are in violation of Hawaii Revised Statues §§ 480-2, 480-3, and 480-4.

f. Iowa: the aforementioned practices by Defendants were and are in violation of Iowa Code §§ 553.1 *et seq.*;

g. Kansas: The aforementioned practices by Defendants were and are in violation of the Kansas Monopolies and Unfair Trade Act, Kan. Stat. Ann §§ 50-101, *et seq.*, and the Kansas Consumer Protection Act, Kan. Stat. Ann §§ 50-623, *et seq.*;

h. Maine: The aforementioned practices by Defendants were and are in violation of the Maine Monopolies and Profiteering Statute, Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*, and the Maine Unfair Trade Practices Act, Me. Rev. Stat. Ann. tit, 5, §§ 205-A, *et seq.*;

i. Massachusetts: The aforementioned practices by Defendants were and are in violation of the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A;

j. Michigan: The aforementioned practices by Defendants were and are in violation of the Michigan Antitrust Reform Act, Mich. Comp. Laws §§ 445.771, *et seq.*, and the Michigan Consumer Protection Act, §§ 445.901, *et seq.*;

k. Minnesota: The aforementioned practices by Defendants were and are in violation of the Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.49, *et seq.*, and the Minnesota Consumer Fraud Act, Minn. Stat §§ 325F.67, *et seq.*;

l. Nebraska: The aforementioned practices were and are in violation of Nebraska Rev. Stat. §§ 59.801 *et seq.*;

m. Nevada: The aforementioned practices by Defendants were and are in violation of the Nevada Unfair Trade Practices Act, Nev. Rev. Stat. §§ 598A.010, *et seq.*, and the Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. §§ 598.0903, *et seq.*;

n. New Mexico: The aforementioned practices by Defendants were and are in violation of the New Mexico Antitrust Act, N.M. Stat. Ann. §§ 57-1-1, *et seq.*, and the New Mexico Unfair Practices Act, N.M. Stat. Ann. §§ 57-12-1, *et seq.*;

o. New York: The aforementioned practices by Defendants were and are in violation of the Donnelly Act, N.Y. Gen. Bus. Law §§ 340, *et seq.*, and the New York Deceptive Acts and Practices Act, N.Y. Gen. Bus. Law §§ 349, *et seq.*;

p. North Carolina: The aforementioned practices by Defendants were and are in violation of North Carolina's antitrust and unfair competition law, N.C. Gen. Stat. §§ 75-1, *et seq.*;

q. North Dakota: The aforementioned practices by Defendants were and are in violation of the North Dakota Antitrust Act, N.D. Cent. Code §§ 51-08.1-01, *et seq.*, and the North Dakota Consumer Fraud Act, N.D. Cent. Code §§ 51-15-01, *et seq.*;

r. South Dakota: The aforementioned practices of Defendants were and are in violation of South Dakota's antitrust law, S.D. Codified Laws §§ 37-1-3, *et seq.*, and deceptive trade practices and consumer protection law, S.D. Codified Laws §§ 37-24-1, *et seq.*;

s. Tennessee: The aforementioned practices of Defendants were and are in violation the Tennessee Trade Practices Act, Tenn. Code Ann. §§ 47-25-101, *et seq.*, and the Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101, *et seq.*;

t. Vermont: The aforementioned practices of Defendants were and are in violation of the Vermont Consumer Fraud Act, Vt. Stat. Ann. tit. 9, §§ 2451, *et seq.*;

u. West Virginia: The aforementioned practices by Defendants were and are in violation of the West Virginia Antitrust Act, W.Va. Code §§ 47-18-1, *et seq.*, and the West Virginia Consumer Credit and Protection Act, W. Va. Code §§ 46A-6-101, *et seq.*; and

v. Wisconsin: The aforementioned practices by Defendants were and are in violation of the Wisconsin Antitrust Act, Wis. Stat. §§ 133.01, *et seq.*, and the Wisconsin Unfair Trade Practices Act, Wis. Stat. § 100.20, *et seq*.

161. As a result of the conduct described above, Plaintiffs and the Class have sustained and will continue to sustain substantial losses to their businesses and their property in the form of, inter alia, being deprived of the ability to purchase less expensive, generic versions of Toprol-XL, and paying for metoprolol succinate at higher prices than they would have been but for Defendants' actions. The present amount of such damages is presently unknown but will be determined through discovery and presented at trial.

162. Plaintiffs and the Class seek damages, multiple damages, treble damages, and other damages permitted by state law, for the injuries caused by Defendants' unlawful actions pursuant to the aforementioned state statutes.

COUNT III

FOR UNFAIR AND DECEPTIVE TRADE PRACTICES UNDER STATE LAW

163. Plaintiffs incorporate by reference and reallege the preceding paragraphs of this Complaint as if fully set forth herein.

164. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below when they filed baseless patent infringement actions against the generic manufacturers in order to prevent the FDA from granting final approval of pending applications of would-be competitors to market generic Toprol-XL. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiffs and class members were deprived of the opportunity to purchase a generic version of Toprol-XL, and were forced to pay higher prices for Toprol-XL during the Class Period.

a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;

b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq.*;

c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200, *et seq.*;

e. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

f. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

g. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;

h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of D.C. Code § 28-3901, *et seq.*;

i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Stat. § 10-1-392, *et seq.*;

k. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

l. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;

m. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, *et seq.*;

n. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

o. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

p. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;

q. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*;

r. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

s. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

t. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

u. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 8.31, *et seq.*;

v. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Missouri Stat. § 407.010, *et seq.*;

w. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;

x. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

y. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

z. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

aa. Defendants have engaged in unfair competition or unfair, unconscionable or deceptive acts or practices in violation of N.J. Rev. Stat. § 56:8-1, *et seq.*;

bb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. § 57-12-1, *et seq.*;

cc. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349 *et seq.*;

dd. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

ee. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

ff. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*;

gg. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of Okla. Stat. 15 § 751, *et seq.*;

hh. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

ii. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

jj. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, *et seq.*;

kk. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

ll. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

mm. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

nn. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

oo. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code § 13-11-1, *et seq.*;

pp. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 9 Vt. § 2451, *et seq.*;

qq. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;

rr. Defendants have engaged in unfair competition or unfair, deceptive or fraudulent acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*; and

ss. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of West Virginia Code § 46A-6-101, *et seq.*

165. Plaintiffs and members of the class have been injured in their business and property by reason of Defendants' anticompetitive, unfair or deceptive acts alleged in this Count. Their injury consists of paying higher prices for Toprol-XL than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

COUNT IV

FOR RESTITUTION, DISGORGEMENT AND IMPOSITION OF A CONSTRUCTIVE TRUST FOR UNJUST ENRICHMENT BY DEFENDANTS

166. Plaintiffs incorporate by reference herein and reallege all preceding paragraphs of this Complaint as if fully set forth herein.

167. Defendants have benefited from the supracompetitive and artificially inflated prices and monopoly profits on their sale of Toprol-XL resulting from their unlawful and inequitable acts alleged in this Complaint.

168. Defendants' financial benefits resulting from their unlawful and inequitable conduct resulted from and are economically traceable to overpayments for Toprol-XL by Plaintiffs and members of the Class.

169. Plaintiffs and the Class have conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiffs and the Class.

170. The economic benefit of overcharges and unlawful monopoly profits derived by Defendants through charging supracompetitive and artificially inflated prices for Toprol-XL is a direct and proximate result of Defendants' unlawful practices.

171. The financial benefits derived by Defendants rightfully belong to Plaintiffs and the Class, as Plaintiffs and the Class paid anticompetitive and monopolistic prices during the Class Period, inuring to the benefit of Defendants.

172. It would be inequitable and unjust for Defendants to be permitted to retain any of the unlawful proceeds resulting from illegally or inequitably obtaining the patents, or illegally or wrongfully listing them in the Orange Book or from the commencement or maintenance of baseless patent infringement lawsuits.

173. It would be inequitable for the Defendants to be permitted to retain any of the overcharges for Toprol-XL derived from Defendants' unfair and unconscionable methods, acts and trade practices alleged in this Complaint.

174. Defendants should be compelled to disgorge to a common fund for the benefit of Plaintiffs and the Class all unlawful or inequitable proceeds received by them.

175. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiffs and the Class.

176. Plaintiffs and the Class and have no adequate remedy at law.

WHEREFORE, Plaintiffs respectfully request that this Court enter an Order:

A. certifying the Class (or subclasses) pursuant to the Federal Rules of Civil Procedure, certifying Plaintiffs as the representatives of the Class (or subclasses), and designating their counsel as counsel for the Class (or subclasses);

B. declaring the '161 and 154 patents invalid, and declaring its listing in the Orange Book invalid and a violation of §2 of the Sherman Act;

C. declaring the '161 and '154 patents invalid, and declaring their listing in the Orange Book invalid and a violation of the antitrust and/or deceptive practices statutes in the Indirect Purchaser states;

D. declaring that Defendants' commencement and/or maintenance of patent infringement lawsuits against filers of ANDAs for Toprol-XL baseless and a violation of § 2 of the Sherman Act;

E. declaring the Defendants' commencement and/or maintenance of patent infringement lawsuits against filers of ANDAs for Toprol-XL baseless and a violation of the antitrust and/or deceptive practice statutes in the Indirect Purchaser States;

F. enjoining and restraining Defendants' continuing violations of § 2 of the Sherman Act, pursuant to § 16 of the Clayton Act;

G. granting Plaintiffs and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;

H. granting Plaintiffs and the Class damages or multiple damages as permitted by law;

I. granting Plaintiffs and the Class their costs of prosecuting this action, together with interest and reasonable attorneys' fees, experts' fees and costs; and

J. granting such other relief as this Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiffs demand a trial by jury of all issues so triable in this case.

Dated: June 5, 2006

By: _____

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CERTIFICATE OF SERVICE

I, J. Clayton Athey, hereby certify that on June 5, 2006, I electronically filed the foregoing CONSOLIDATED CLASS ACTION COMPLAINT with the Clerk of the Court using CM/ECF, and caused notification of such filing to be sent to the following counsel of record:

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